and *Eibel* – that decision should be made by this Court. But, because the Federal Circuit has exclusive jurisdiction over patent appeals, its erroneous ruling will distort patent law and policy unless and until this Court intervenes. Accordingly, this petition should be granted.

STATEMENT OF THE CASE

1. The Doctrine Of Inherent Anticipation

Under section 102 of the Patent Act, an invention must be "novel[]" to qualify for patent protection. See 35 U.S.C. § 102. That requirement reflects the basic policies at the heart of patent law. Patent law provides legal protection for "new and useful" products or processes "to foster and reward invention," but "the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public." *Aronson* v. *Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Confining patents to "new" inventions makes sense because non-novel ideas are, by definition, already in the public domain, and no one needs an inducement to "discover" them. See *Pfaff* v. *Wells Elecs. Inc.*, 525 U.S. 55, 64 (1998).

An invention is not novel, and does not qualify for patent protection, if it is "anticipated" by any "prior art reference" – *e.g.*, if all of the elements of the invention are "described" in a prior patent or publication. 35 U.S.C. § 102(a); see, *e.g.*, *Glaverbel Societe Anonyme* v. *Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). Anticipation can be either explicit, as when the prior art reference expressly describes each aspect of the later invention, or "inherent." As one treatise explains, a prior art reference can inherently anticipate "something not expressly stated" only if (i) "the missing subject matter is 'necessarily present' in what *is* expressly described in the reference," *and* (ii) "a person of

ordinary skill in the art would recognize this." J. Mueller, *An Introduction To Patent Law* 99 n.20 (2003).[1]

In numerous cases, a process or product has been inherent in the prior art, but has been held not to be appreciated and thus not to have been "anticipated." In these cases, courts have characterized the presence of the product or the process in the prior art as "accidental," "unwitting," or "unappreciated," and have concluded that the prior art does not anticipate and thus does not bar a new patent under section 102. This limitation on the doctrine of inherent anticipation is referred to as accidental or unwitting prior use. See J. Kilyk, Jr., *Accidental Prior Use*, 64 J. Pat. Off. Soc'y 392, 392 (1982).[2] See also 1 D. Chisum, *Chisum on Patents*, § 3.03, at 3-67 (2003).

2. Factual Background

This litigation concerns paroxetine hydrochloride, the active ingredient in the antidepressant Paxil.® For present purposes, this compound appears in two distinct crystalline forms, known as "polymorphs": (i) "PHC" *anhydrate*, which

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[1] The concepts of anticipation and novelty, which arise under section 102 of the Patent Act, should not be confused with the distinct concept of "nonobviousness," which arises under section 103. An invention can be technically "novel" (because no prior art reference described each of its elements) but nonetheless "obvious" and unpatentable. The test for obviousness is whether the prospective patent's subject matter "as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a); *see generally Bonito Boats Inc.* v. *Thunder Craft Boats Inc.*, 489 U.S. 141, 151, 156 (1989).

[2] This limitation on inherent anticipation is also sometimes inaptly referred to as "accidental anticipation." Because there is no recognition or appreciation of all of the elements of the claimed invention in accidental prior use, there is no anticipation in any commonly understood sense of the term. To avoid that confusion, the petition uses the terms "accidental," "unwitting," or "unappreciated" "prior use" instead of "accidental anticipation."

contains no water molecules in its crystal structure; and (ii) PHC *hemihydrate*, which contains one water molecule for every two molecules of paroxetine hydrochloride bound in the crystal.[3]

The PHC anhydrate form's water content varies depending upon environmental conditions because it attracts water molecules from the air, which typically sit loosely on the outside of the paroxetine hydrochloride molecules. App. 116a. In contrast, the PHC hemihydrate form presents few such concerns because, as the district court observed, "it is not 'thirsty' – it has already drunk, as it were." *Id.*

In 1977, a European company called Ferrosan obtained a U.S. patent (No. 4,007,196) on a set of compounds that included what is now known as paroxetine. This 1977 patent is the "prior art reference" that, according to the Federal Circuit majority, "anticipates" the hemihydrate and thus invalidates the subsequent patent on the hemihydrate (No. 4,721,723), which SmithKline Beecham applied for in 1985 and obtained in 1988.[4]

The 1977 Ferrosan patent, however, did not mention the hemihydrate; indeed, it did not even mention "paroxetine

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[3] The hemihydrate and the anhydrate are "bioequivalent" in the sense that, although they posses different properties, they have identical effects on the body. In other cases, however, a new crystalline form of the same compound can have dramatically different pharmaceutical effects. *See* App. 123a-124a; S. Chemburkar et al., *Dealing with the Impact of Ritonavir Polymorphs on the Late Stages of Bulk Drug Process Development*, 4 Organic Process Res. & Dev. 413, 413-17 (2000).

[4] The opinions below refer to the first of these patents as the "'196 patent" and the second as the "'723 patent," in each case citing the final three digits of the patent number assigned by the Patent and Trademark Office. For ease of exposition, we use the terms "Ferrosan patent" to refer to the '196 patent, and the terms "SmithKline Beecham patent" or "hemihydrate patent" to refer to the '723 patent and, in particular, to its first claim, which reads: "Crystalline paroxetine hydrochloride hemihydrate."

hydrochloride." It is undisputed, moreover, that no one knew that the hemihydrate even existed before a SmithKline Beecham employee discovered it in 1985. App. 9a, 15a, 17a. And, it is likewise undisputed that, until this 1985 discovery, a specialist in the field, even if familiar with the technology described in the Ferrosan patent, could not predict the existence of the hemihydrate, how to make it, or what distinct properties it would have. *Id.* Nevertheless, the Federal Circuit majority held that the Ferrosan patent "anticipated" the hemihydrate patent because many manufacturers cannot now feasibly make anhydrate without producing at least trace amounts of hemihydrate. *Id.* at 20a. But if (as the majority believed) that fact was true 20 years ago when hemihydrate itself was discovered, it was completely unknown to the entire scientific community at the time, and no one argues otherwise. *Id.* at 9a, 15a, 17a..

3. Proceedings Below

In 1998, SmithKline Beecham sued respondent Apotex, another pharmaceutical manufacturer, for infringing the hemihydrate patent. Apotex denied the infringement and challenged the validity of the patent. After discovery and initial proceedings before Chief Judge Kocaras of the Northern District of Illinois, the case proceeded to trial before Circuit Judge Richard Posner, sitting by designation.

In 2003, after a three-week trial, the district court upheld the validity of the hemihydrate patent. Judge Posner rejected as "frivolous" Apotex's claim that the 1977 Ferrosan patent "literally" anticipated the hemihydrate patent at issue here, observing that there "is no mention of hemihydrate in the patent . . . and the hemihydrate polymorph of paroxetine was unknown either when the [Ferrosan] patent application was filed or in 1977 when the patent was granted." App. 131a. Judge Posner then rejected Apotex's argument that the Ferrosan patent "inherently" anticipated the hemihydrate patent, reasoning that the "serendipitous appearance of a polymorph years after another polymorph of the same crystal

is patented does not prove to the requisite degree of certainty that the new polymorph was inherent in the old." *Id.* at 132a. Nonetheless, based on his own narrowing construction of the hemihydrate patent, he ruled that Apotex had not infringed it. *Id.* at 142a.

SmithKline Beecham appealed on the claim construction and related infringement issues. Apotex cross-appealed, once more contending, among other things, that the hemihydrate patent is invalid. In its briefs, however, Apotex did *not* contest the district court's rejection of its "inherent anticipation" theory. Instead, it challenged the patent's validity only on the unrelated theory, which the district court had also rejected, that certain pre-patent clinical trials amounted to a "public use" of PHC hemihydrate and thereby undermined its patentability.

In its first opinion, the Federal Circuit rejected the district court's narrowing construction of the hemihydrate patent and held that Apotex had infringed it. The panel majority nonetheless deemed the patent invalid under Apotex's "public use" theory – *viz.*, the theory that the hemihydrate was in "public use" for more than a year prior to the patent application date. App. 82a.

On June 4, 2004, SmithKline Beecham filed a petition for rehearing *en banc*, asserting that the panel had applied the public-use bar in a manner that conflicted with numerous prior decisions of the Federal Circuit. Apotex filed a conditional cross petition for rehearing *en banc*, claiming that if the court were to grant review, it should also consider issues of claim construction and infringement raised in the conditional cross-petition.

On April 8, 2005, the court granted rehearing *en banc* "for the limited purpose of vacating the panel's original opinion addressing the issue of experimental use." App. 57a. It then remanded "to the panel for further proceedings." *Id.*

On the same day, however, the panel majority issued its decision on remand, replacing its earlier theory of invalidity with a theory of inherent anticipation – the very theory that, as the panel itself had previously observed, Apotex had declined to present on appeal. App. 73a. In finding inherent anticipation, the majority reasoned that "producing [PHC] anhydrate according to the [1977 Ferrosan] patent inevitably results in the production of at least trace amounts of . . . hemihydrate." *Id.* at 19a. That fact, the majority reasoned, is sufficient to invalidate the hemihydrate patent, even though no one knew until the 1985 discovery claimed in that patent that the hemihydrate even existed. In a holding with vast implications for patent law, the majority declared: "inherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created." *Id.* at 18a.

Judge Gajarsa concurred in the judgment only. He expressly declined to join the majority's "inherent anticipation" theory and argued instead that the patent is invalid on "unpatentability" grounds under 35 U.S.C. § 101 (App. 25a-55a), a view that the majority tersely dismissed as implausible (*id.* at 16a-17a).

Judge Newman, however, dissented from the decision to limit the *en banc* court's review to the "public use" theory, observing that, on remand, the panel was simultaneously making nonsense of the inherent anticipation doctrine:

> Invalidity based on "anticipation," 35 U.S.C. § 102, requires that the identical invention was known or its existence would reasonably have been known to a person of ordinary skill in the field of the invention – not that it might have lain hidden in minuscule amount, undetected, unsuspected, and unknown. . . .
>
> [But] [t]he panel now holds that a product that existed in trace amounts, although unknown and undetected and unisolated, is "inherently anticipated" and barred from

> the patent system after it is discovered. [App. 58a-59a (citations omitted).]

That holding, Judge Newman observed, is flatly at odds with a line of controlling authority stretching back to this Court's decision in *Tilghman*. App. 59a. She added that the majority's holding is untenable as a matter of national patent policy, both because it "giv[es] rise to uncertainty as to existing patents" whose validity had never before been doubted and because it undermines the incentives of potential inventors to "search[] for the beneficial components of existing materials." *Id.*

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW CONTRAVENES DECISIONS OF THIS COURT AND ESTABLISHED PATENT LAW.

A claimed invention may be inherently anticipated by a prior art disclosure if the claimed invention necessarily or inevitably flows from the prior art. This Court, however, has long recognized that inherent anticipation does not apply if the prior art accidentally or unwittingly presents the claimed subject matter. See *Tilghman* v. *Proctor*, 102 U.S. 707 (1881); *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403 (1902); *Eibel Process Co.* v. *Minnesota & Ont. Paper Co.*, 261 U.S. 45 (1923). "Courts have been applying the doctrine of accidental prior use for at least the preceding one hundred years." Kilyk, Jr., *supra*, at 392.

In this case, the Federal Circuit invalidated SmithKline Beecham's patent claim covering PHC hemihydrate, the active ingredient in the antidepressant Paxil®, on the ground that the claim was "invalid for inherent anticipation," and thus was not "novel" within the meaning of section 102(b), based on a 1977 patent that disclosed paroxetine, but did not describe the PHC hemihydrate. Indeed, no one, including those skilled in the art, knew that the PHC hemihydrate even

existed until the 1985 discovery embodied in the SmithKline Beecham patent. The Federal Circuit nonetheless concluded that the 1977 Ferrosan patent inherently anticipated SmithKline Beecham's hemihydrate claim because it is now the case that producing the anhydrate "inevitably results in the production of at least trace amounts of . . . hemihydrate." App. 19a. Established precedent of this Court and the lower courts, however, makes clear that the prior art can inherently anticipate only if a person of ordinary skill in the art could recognize the inherent disclosure in the prior art before the new discovery or invention occurs. Thus, clearly, a prior accidental, unrecognized coproduction of a minuscule amount of a substance unknown in the prior art does *not* inherently anticipate, and thus does not preclude a patent on the later discovery or invention of the same undisclosed, unappreciated and unrecognized substance.

The seminal case is *Tilghman*. There, the patent claimed a process for separating "'fatty bodies'" into their components: "'fat acids and glycerine.'" 102 U.S. at 709. Several previously patented processes resulted in the same separation, but this Court nonetheless held:

> We do not regard the accidental formation of fat acid in [another device] as of any consequence in this inquiry. What the process was by which it was generated or formed was never fully understood. Those engaged in the art of making candles, or in any other art in which fat acids are desirable, certainly never derived the least hint from this accidental phenomenon in regard to any practicable process for manufacturing such acids. [*Id.* at 711.]

Thus, in words critical here, the Court concluded:

> [i]f the acids were accidentally and unwittingly produced, whilst the operators were in pursuit of other and different results, *without exciting attention and without its even being known what was done or how it*

> *had been done*, it would be absurd to say that this was an anticipation of Tilghman's discovery. [*Id.* at 711-12 (emphasis supplied)].

In *Eibel Process Co.* this Court again addressed accidental prior use, this time in connection with the patenting of a machine rather than a process. Eibel's patent involved an improved machine for production of paper for newsprint; the improvement was that, by elevating a part of the machine to add pitch, one could achieve a significant increase in the machine's speed. The accused infringer argued that Eibel's invention had been anticipated by the devices of two other inventors, regardless of whether those inventors had "perceived the advantage of speeding up the stock" that Eibel claimed, because the "necessary effect of their devices was to achieve that result and therefore their machine anticipated" Eibel's new invention. 261 U.S. at 66. This Court rejected that argument, explaining that even if the alleged infringer demonstrated that the prior devices accomplished results identical to those achieved by Eibel, such "accidental results" of prior art that are "not intended and not appreciated, do not constitute anticipation." *Id.*

A. Unrecognized Results Of Prior Art Are Not Inherently Anticipated.

Tilghman and *Eibel* thus make clear that a party claiming inherent anticipation must show not only that the claimed invention is necessarily disclosed in the prior art, but also that a person of ordinary skill in the art would recognize that fact. See also *Carnegie Steel Co.*, 185 U.S. at 429-30 (holding that a claim was not inherently anticipated by a prior patented process in part because that subject matter of the claim had never before been appreciated in the art). Following this Court's teaching, the federal courts, including until recently the Federal Circuit, routinely opined that there could be no inherent anticipation based on the unintended, unappreciated results of prior art.

In *Continental Can* v. *Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), for example, the Federal Circuit explained that in order for an unexpressed subject matter of a patent to anticipate a patent claim, a person of ordinary skill in the art must have been able to know or appreciate that inherent subject matter *before* the subsequent claim was made:

> To serve as anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, *and that it would be so recognized by persons of ordinary skill.* [*Id.* at 1268 (emphasis supplied).]

See also, *e.g.*, *In re Seaborg*, 328 F.2d 996, 998-99 (C.C.P.A. 1964) (rejecting claim of inherency where the product "was produced in such minuscule amounts and under such conditions that its presence was undetectable"); *Rosco, Inc.* v. *Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2003) (skilled artisan's recognition of missing descriptive matter required for inherent anticipation); *Crown Ops. Int'l Ltd.* v. *Solutia, Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002) (same); M. O'Neil & G. Ng, *Doctrine of Inherent Anticipation Is Clarified*, Nat'l L. J., Dec. 8, 2003, at S6 (describing widespread judicial interpretation mandating proof of allegedly inherent feature by evidence within the prior art time frame).

Other courts have read this Court's decisions in the same way.[5] And the AIPLA Guide to Jury Instructions in Patent Cases reflects this understanding as well.[6]

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[5] *See American Original Corp.* v. *Jenkins Food Corp.*, 696 F.2d 1053, 1059 (4th Cir. 1980) ("'the prior accidental production of the same thing, where character and function are not recognized does not anticipate'"); *Silvestri* v. *Grant*, 496 F.2d 593, 597 (C.C.P.A. 1974) ("[t]he ampicillin of the count is a new form of an otherwise old composition. It is now well

The Federal Circuit abandoned this Court's limited inherent anticipation doctrine in *Schering Corp.* v. *Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). There, the court held that "anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure" in the prior art at the time the prior art is created. *Id.* at 1377. Thus, the rule of law now embraced by the Federal Circuit is that a patent may inherently anticipate *even a subject matter that was unknown to persons of ordinary skill in the art until the subsequent discovery and claim were made.* The court of appeals has removed the requirement that a person of ordinary skill in the art recognize anything about an invention or discovery, including its existence.[7]

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settled that in such a case there is no conception or reduction to practice where there has been no recognition or appreciation of the existence of the new form."); *id.* ("until they recognized their accomplishment, the preparation of the new form by each of the appellants remained in the accidental and unappreciated category. A fortiori, no right to a patent arose prior to such recognition."); *Dewey & Almy Chem. Co.* v. *Mimex Co.*, 124 F.2d 986, 989 (2d Cir. 1942) (doctrine of inherent anticipation does not apply if the prior art reference "does not inform the art without more how to practice the new invention" and therefore "has not correspondingly enriched the store of common knowledge").

[6] *See* ABA's Section of Patent, Trademark & Copyright Law, *AIPLA Guide To Jury Instructions in Patent Cases* § 4.4 (1987) (instructing that "[t]here cannot be an accidental or unrecognized anticipation. A prior duplication of the claimed invention that was accidental, or unrecognized, unappreciated and incidental to some other purpose is not an invalidating anticipation.") (citing, *inter alia*, *Tilghman, North Caroline* v. *Chas. Pfizer & Co.*, 384 F. Supp. 265 (E.D.N.C. 1974); *United States* v. *Pfizer, Inc.*, 498 F. Supp. 28 (E.D. Pa. 1980)).

[7] In *Schering*, the Federal Circuit claimed that *Continental Can* did not hold that prior recognition of the inherent feature is required for anticipation, 339 F.3d at 1377, but "[t]his interpretation appears inconsistent with Judge Newman's explicit statement in *Continental Can*." A. Brown & M. Polyakov, *The Accidental and Inherent Anticipation Doctrines: Where Do We Stand and Where Are We Going?*, 4 J. Marshall

The decision below reinforces and improperly extends the *Schering* holding. *Schering* wrongly held that inherent anticipation can apply even if people of ordinary skill in the art did not recognize the existence or the structure of the new substance. The *Schering* court reasoned that the undisclosed compound necessarily was formed in detectable amounts when a person ingested the disclosed compound, based on well understood chemical principles. See *id.* at 1378. The decision below, however, added the further gloss to *Schering* that inherent anticipation applies even if no person ordinarily skilled in the art could have known that the new substance would exist or could be formed. Put differently, the Federal Circuit has concluded that even if the prior art would not have resulted in the production of the new substance based on its teachings and the general knowledge in the art (because the substance may not have existed then), the prior art can inherently anticipate if it inevitably results in the production of the new substance *now*. This broad notion of inherent anticipation allows a process to anticipate each and every trace compound that could possibly result from the process at any point in time, including after the patenting of the newly discovered trace compound.

The Federal Circuit's approach contradicts not simply the letter but the spirit of this Court's cases. This Court limited the doctrine of inherent anticipation because an unintended, unappreciated, and undisclosed feature of the prior art provides no benefit to the public. Granting a patent to an applicant who subsequently detects and explains the practical value of the previously undisclosed and unappreciated invention is fully justified because the public, by such patenting, gains knowledge of that process or product and its value. Cf. also *Aronson*, 440 U.S. at 262 (patent law seeks to protect and reward "new and useful" products and processes). If the recognition requirement is eliminated, then a product

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Rev. Intell. Prop. L. 63, 82 (2004) (citing *Continental Can*, 948 F.2d at 1269).

will be inherently anticipated any time it is the unknown, unintended, unappreciated result of practicing the prior art, and there will be no incentive to discover or develop the new products and processes that may inhere in prior art.

Although *Schering* and the decision below each purports to distinguish *Tilghman* and *Eibel*, the decisions cannot be reconciled. The Federal Circuit asserts that in *Tilghman* and *Eibel*, it was not certain, but instead only possible that the prior art produced the claimed subject matter. This supposed distinction "is somewhat misleading, however, since in those cases, certainty was not the dispositive issue. Instead, the dispositive issue was that, even if the event had occurred, it was unintended, unappreciated, not recognized, and not useful, and therefore, did not rise to the level of legal anticipation." A. Brown & M. Polyakov, *The Accidental and Inherent Anticipation Doctrines: Where Do We Stand and Where Are We Going?*, 4 J. Marshall Rev. Intell. Prop. L. 63, 81 (2004). Both *Tilghman* and *Eibel* assumed that the prior art inevitably produced the new product, but nonetheless held that the product was not anticipated because the earlier production was unintended and unappreciated. The Federal Circuit has disregarded holdings of this Court, which it clearly may not do. Indeed, "carefully considered language of the Supreme Court, *even if technically dictum*, generally must be treated as authoritative." *Sierra Club* v. *EPA*, 322 F.3d 718, 724 (D.C. Cir. 2003) (emphasis added; internal quotation marks and citation omitted).[8]

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[8] *Accord, e.g.*, *McCalla* v. *Royal MacCabees Life Ins. Co.*, 369 F.3d 1128, 1132 (9th Cir. 2004); *Wynne* v. *Town of Great Falls*, 376 F.3d 292, 298 n.3 (4th Cir. 2004), *cert. denied*, 125 S. Ct. 2990 (2005); *Crowe* v. *Bolduc*, 365 F.3d 86, 92 (1st Cir. 2004); *Johnson* v. *McKune*, 288 F.3d 1187, 1199 (10th Cir. 2002).

B. The Decision Below Cannot Be Reconciled With The Undetected Co-product Cases.

Until *Schering* and the decision below, the federal courts uniformly interpreted *Tilghman* to mean that there is no inherent anticipation where, as here, small amounts of a product are the unintended and accidental result of practicing what is disclosed in the prior art "without exciting attention and without its even being known what was done or how it had been done." 102 U.S. at 711-12. In a series of cases, the federal courts have made clear that a prior, unrecognized co-production of a product accidentally and unwittingly resulting from practicing the prior art will not bar a patent on a later invention or discovery of the same product.

This particular manifestation of *Tilghman's* accidental prior use doctrine was clearly explained in *Ritter* v. *Rohm & Haas Co.*, 271 F. Supp. 313, 145-46 (S.D.N.Y. 1967). There, Ritter sought to patent a process for the production of certain amides, a type of organic compound. The process was already known to have produced esters, but it had not been appreciated that the amides had also been produced. *Id.* at 346. The court held that the prior art did not bar a patent on the production of that unknown co-product:

> where products are 'unwittingly produced, whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done, it would be absurd' to hold that this is anticipation. It is one thing to say that a rose by any other name is still a rose. It is far different to assert that the discovery of a rose means discovery of a bee which happens, incidentally, to be lost in its petals. [*Id.* at 345-46 (quoting *Tilghman*, 102 U.S. at 712)].

Even more directly on point is a series of cases involving the prior accidental and unrecognized co-production of minuscule amounts of tetracycline in connection with the

production of Aureomycin. When the inventor of tetracycline sought a patent, others argued that the prior process used to produce Aureomycin inherently anticipated the tetracycline claim. Relying on *Tilghman*, all courts to consider the question held that the prior art did not anticipate tetracycline because the co-production of that substance had been unappreciated:

> [c]oproduction of small amounts of tetracycline in the prior art which was unrecognized at the time of the Conover invention could not act as a bar to a patent on tetracycline. [*In re Coordinated Pretrial Proceedings*, 498 F. Supp. 28, 35 (S.D.N.Y.), *aff'd*, 676 F.2d 51 (3d Cir. 1980)].

See also *North Carolina* v. *Chas. Pfizer & Co.*, 384 F. Supp. 265, 278 n.17 (E.D.N.C. 1974) ("prior accidental and unrecognized co-production of small amounts of tetracycline with Aureomycin did not render the claim to tetracycline unpatentable"), *aff'd*, 537 F.2d 67 (4th Cir. 1976).[9]

In *Seaborg*, the Federal Circuit's predecessor court properly applied *Tilghman* to a case involving unintended and unappreciated co-production. The court rejected the argument that a patent on nuclear reactor technology inherently anticipated the creation of the chemical element Americium, explaining that if Americium "was produced in the [patented] process, [it] was produced in such minuscule amounts and under such conditions that its presence was

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[9] *See* 384 F.Supp. at 278 n.17 ("'novelty is not negatived by any prior accidental occurrence or production, the character and function of which was not recognized until later than the date of the patented invention sought to be anticipated thereby,' 1 Walker, Patents, 6th ed. § 106'") (citing *Kuehmsted* v. *Farbenfabriken*, 179 F. 701 (7th Cir. 1910); *Parke, Davis & Co.* v. *H.K. Mulford Co.*, 180 F. 95 (C.C.S.D.N.Y. 1911), *aff'd in part, rev'd in part on other grounds*, 196 F. 496 (2d Cir. 1912)); *Chas. Pfizer & Co.* v. *Barry-Martin Pharms., Inc.*, 241 F. Supp. 191, 194 (S.D. Fla. 1965) ("the prior existence of tetracycline in Aureomycin in trace amounts, unrecognized and of no use does not invalidate the patent").

undetectable." 328 F.2d at 998-99. *Seaborg* cannot be reconciled with the decision below:

> Seaborg's claims to Americium were upheld despite the fact that some small and undetectable amounts of Americium were inherently produced in the prior art as a by-product of a different process. The [court] stated that the undetectable isotope did not enrich "the store of common knowledge" and was not an anticipation. However, if the . . . rationale [in the instant case] is applied, practicing the prior art process of producing minuscule amounts of Americium as a by-product would infringe the patent to Americium, and the patent to Americium must be anticipated by these tiny undetected amounts of Americium. [Brown & Polyakov, *supra* at 88.[10]]

In sum, until recently, this Court's decisions in *Tilghman* and *Eibel* had been uniformly interpreted to "establish[] that in an unknown coproduction situation, the prior use of a process to produce compound A does not constitute an anticipatory bar to a patent claiming the identifiable process to produce compound B *nor a patent claiming the product, compound B, of the process*." Kilyk Jr., *supra* at 406 (emphasis supplied). In this respect, too, the decision below contravenes established precedent and merits this Court's review.[11]

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[10] In *Schering*, the Federal Circuit purported to distinguish *Seaborg* on the ground that the co-product in *Seaborg* was undetectable. 339 F.3d at 1379. In the decision below, however, the court concluded that an undetectable co-product can anticipate. *See* App. 22a. For this reason, too, the rationale of the decision below conflicts with that of *Seaborg* and fundamentally alters established patent law.

[11] This case would be different, of course, if the discovery were not of a new product, but of a new benefit of an old product. The discovery that aspirin is useful in treating heart disease would not permit anyone to patent aspirin itself and thereby remove it from the public domain. "A newly rediscovered attribute or property of something that was already

II. THE ISSUE PRESENTED IS RECURRING AND IMPORTANT.

For several reasons, it is critically important that this Court address the recurring and fundamental questions of patent law that arise in this case.

First, the Federal Circuit's exclusive appellate jurisdiction over patent disputes, see 28 U.S.C. § 1295(a)(4), ensures that the issue raised in this case will not be further vetted in the lower courts. Only this Court can correct the erroneous holding below and restore the integrity of its own precedents.

Second, the conflict between the decision below and this Court's decisions addressing the line between inherent anticipation and accidental prior use is reflected in a profound disagreement among the judges of the Federal Circuit. In *Schering*, Judges Newman, Lourie, and Gajarsa all voted for rehearing *en banc*, to no avail. Judge Newman dissented from the denial of rehearing on the ground that the panel had erroneously expanded the doctrine of inherent anticipation "to bar the patentability of products that have not yet been discovered." 348 F.3d 992, 995 (Fed. Cir. 2003). Judge Lourie, too, dissented because the panel had issued "an extraordinary decision" concerning "an issue of exceptional importance" and had gotten it wrong. *Id.* at 994. Judge Newman again expressed her dissenting view in this case, objecting to the *en banc* court's exclusion of the anticipation question from the scope of its review and observing that the panel majority was wrong and that its decision conflicted with *Tilghman* and *Eibel*. App. 57a-59a.

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known is patentable only as a method-of-use, but does not impart patentability to the known product. However, *a previously unknown product does not become unpatentable simply because it existed before it was discovered.*" *Schering Corp.* v. *Geneva Pharms, Inc.*, 348 F.3d 992, 994 (Fed. Cir. 2003) (Newman, J., dissenting from denial of rehearing *en banc*) (emphasis added).

The dissenting judges also recognized that unless the Federal Circuit's erroneous legal ruling is corrected, its error will thwart settled expectations and threaten the innovation that the patent laws are designed to protect. As Judge Newman explained, "[t]he patentability of antibiotics, hormones, antibodies, and myriad other previously unknown or unisolated products would be called into question by this new ruling, giving rise to uncertainty as to existing patents, as well as negation of searches for the beneficial components of existing materials." App. 59a. See also *Schering*, 348 F.3d at 995-96 (the court's unprecedented expansion of the anticipation doctrine "effectively preclud[es] virtually all patents on human metabolites of drugs," a consequence that "cannot be correct"). There is, accordingly, a substantial division among the judges of the only court with jurisdiction over patent appeals on an issue that those expert judges clearly deem important. That conflict should be resolved by this Court.

Third, the Federal Circuit's doctrine of inherent anticipation will have a profound and damaging impact on patent law and undermine its purposes, as the Federal Circuit's dissenting judges have decried. The Federal Circuit's sweeping inherent-anticipation doctrine calls existing patents into question and discourages investment in the development and discovery of new products. Professor Donald Chisum, author of the leading patent law treatise, has observed that the Federal Circuit's "broad" new doctrine of inherent anticipation "seems to allow a described process to anticipate every compound X that could result from that described process, based on later evidence that practicing the process produces at least a trace amount of X, whether or not X was relevant, expected, or detected." D. Chisum & M. Smith, *SmithKline: How the Expanding Inherent Anticipation Doctrine Affects Chemical Patents*, *IP Newsletter* (Morrison/Foerster, S.F., Cal.), June, 2005, at 4, *available at* http://www.mofo.com/

docs/PDF/IPNewsletter0605.pdf. As a policy matter, moreover,

> it is not clear that a broad inherent anticipation rule is good: it places patentees in the uncomfortable position of not knowing whether their patents might be invalidated by a reference, perhaps not even closely related to their own research. For example, a patent on a new compound with pharmaceutical activity could be invalid if the compound was later shown to be a metabolite of some other drug, even if the other drug was used for a seemingly unrelated purpose. [*Id.* at 5.]

"Such heightened uncertainty," Professor Chisum concludes, "reduces incentives for research and for disclosure in the form of patents." *Id.*; see also App. 59a (Newman, J., dissenting) (Federal Circuit's decision undermines incentives of potential inventors to "search[] for the beneficial components of existing materials").

The detrimental consequences of uncertainty broadly affect innovation involving manufacturing and chemical products (as *Tilghman* and *Eibel* illustrate), but they are particularly debilitating for the pharmaceutical industry. A recent study and analysis concluded that the approximate costs of obtaining approval for a pharmaceutical drug from the Food and Drug Administration to be marketed in the United States is $1.7 billion. P. Landers, *Cost of Developing a New Drug Increases to About $1.7 Billion*, Wall St. J., Dec. 8, 2003, at B.4. These are extraordinary costs, and the willingness of chemical and biotechnology companies to invest such sums will be substantially decreased if a patent can be invalidated by the revelation that the product is an unrecognized, but inevitably-produced byproduct of some prior art process or compound – especially when this is first shown long after the patent is granted. The full results of experiments that produce chemical or biotechnology drugs may not be seen or appreciated for many years after the initial experiment and its results are patented. Yet, under the Federal Circuit's rule,

such new results will constantly threaten to invalidate existing patents, and patentees will never have any assurance whether and for how long their patents are secure.

This kind of uncertainty inherently reduces incentives for research and disclosure and for product development in all sectors of the economy. It is, therefore, legal error and bad patent policy to allow boundless inherency to prevent a later inventor, who actually did the hard work and solved the problems along the way, from patenting his or her discovery or invention. See also O'Neill & Ng, *supra* at S6 ("a patent to a previously unknown compound may be invalidated as inherently anticipated if the compound is later discovered to be a metabolite of another compound in the prior art"); *id.* (Federal Circuit "has created further controversy and unique challenges in obtaining patent protection in biotechnology and chemical arts").

* * * *

The Federal Circuit's decision vastly expands the doctrine of inherent anticipation and essentially eviscerates this Court's jurisprudence of accidental prior use, thereby undermining the purposes of patent law by stripping away the recognition requirement and finding inherent anticipation in the unknown and unappreciated byproducts of prior art. This Court should grant the petition to forestall this radical departure from established precedent and the harmful consequences for patent law and policy that the Federal Circuit's rule will certainly cause.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 13, 2005

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